

# Accreditation Board Meeting Agenda



**CONFIDENTIAL – AB MEMBERS ONLY**

Thursday, October 10, 2019

8:30 AM - 11:00 AM

Palace Hotel in San Francisco, CA

	<b>Attachment</b>	<b>Presenter</b>	<b>Action?</b>
<b>1. Call to Order</b>		Ketcherside	No
<b>2. Approval of Minutes</b>	A	Stoeger	Yes
<b>3. Old Business</b>			
<b>3a.</b> non-member accreditation discussion		Corcoran	No
<b>3b.</b> Training Update		Stoeger/Mavin	No
<b>3c.</b> Forms Subcommittee Activity Report	B	Binnion	Yes
<b>3d.</b> Scores and scoring – ad hoc committee update- new SIQ developed by Brian Philippy that automatically scores.	C (Excel)	Philippy	No
<b>3e.</b> Use of video in lieu of being on site for training and inspections – update		Ketcherside	No
Remote chart review; Videoconference for MD interview			
<b>3f.</b> AOPO, AATB, EBAA collaboration to reduce auditing burden of shared inspection criteria ad hoc subcommittee update		DeMatteo	No
<b>New Business</b>			
<b>4. 4a.</b> Support for donor database report to aid inspections		Philippy	Yes
<b>4b.</b> Use of electronic versions of SDS binders		Stockman	No
<b>5. Late Additions</b>		Stoeger	
<b>6. Adjournment of Business Meeting</b>		Ketcherside	Yes

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|--|-------------|-----|
| <b>7. Fall 2019 Inspection Cycle</b><br>A scoring sheet will be distributed to all AB members at the beginning of the closed portion of the meeting. | Ketcherside | Yes |
| <b>8. Adjournment</b>  | Ketcherside | Yes |

**Reminders:** Do not mention eye bank names, locations, size or affiliation of banks. Confidentiality must be maintained before, during and after all Accreditation Board meetings. AB members may cast a vote for banks they inspect. AB members are not permitted to vote if their own bank is presented or if they are not present during the inspection presentation.



**ACCREDITATION BOARD MEETING MINUTES**  
**June 6, 2019**  
**Fairmont Scottsdale Hotel in Scottsdale, Arizona**

**I. Call to Order**

Dr. Chris Ketcherside called the meeting to order and welcomed Accreditation Board members and guests in the attendance.

The following members were present:

Christopher Ketcherside, MD	Co-Chair
Chris Stoeger, CEBT	Co-Chair
Kyle Mavin, CEBT	Co-Vice Chair, Training Chair
Michelle Rhee, MD	Co-Vice Chair
Beth Binnion, CEBT	Chair, Forms Subcommittee
Alan Blake, CEBT	
Sara J. Botsay, CEBT	
Lisa Brooks, CEBT	
Jason Brosious, CEBT	
Ryan Cady, CEBT, CTBS	
Winston Chamberlain, MD	
Kevin Corcoran, CAE	President/CEO – EBAA
Jennifer DeMatteo, MCM, CIC	Director of Regulations & Standards – EBAA
Marcella Dimond, CEBT	
Donna Drury, CEBT	
Timothy Fischer, CEBT	
Brian Ha, CEBT	
Erik Hellier, CEBT	
Christopher Hood, MD	
Adam Kaufman, MD	
Ginny Kullman, MD	
Jennifer Li, MD	
Amy Lin, MD	
John Lohmeier, CEBT	
Dan Lunn, CEBT	
Linda Martin, CTBS	
Donna McDonald, CEBT	
Eric Meinecke, CEBT	
Shahzad Mian, MD	

Tom Miller, MS, CEBT  
Brian Philippy, CEBT  
Jim Quirk, CEBT  
Sam Ramos, CEBT, CBTS  
Mijana Ridic, CEBT  
Christopher Sales, MD, MPH  
Adam Stockman, CEBT  
Michael Titus, CEBT  
David Tremblay, MD  
Woodford Van Meter, MD                      EBAA Chair  
David Warner, MD

## **II. Approval of Minutes**

Chris Stoeger requested approval of the minutes from the last meeting.

**Action:** A motion was made (Quirk) and seconded (Meinke) to approve the minutes from the October 2018 meeting in Chicago, IL. **Motion Passed.**

## **III. Old Business**

### **A. Forms Subcommittee – Binnion**

Beth informed the board that a change was performed in the PIQ instructions (e.g. referencing Section 4-G, B1.000) that the word “Maintain” added to state “*Documentation of maintaining registration with ICCBBAA for FIN*”.

### **B. Training Update – Mavin**

Scores and Scoring committee had met and drafted a Training slide deck. The training consists of history as to “why” the scoring is necessary, “what” the scoring entails and “how” to perform the scoring calculation. Kyle presented this training module to the members. A small discussion regarding whether inspectors should provide the preliminary scores to the bank while on site. Kyle stated that it would not be necessary and gave an example that if a PT was noted it may be so severe that it could influence the final decision of the accreditation of that bank (despite having a high score). Jennifer added that the scores are listed on the document that is given to the bank regarding the final accreditation. Lead inspectors are now expected to compute scores and submit them with paperwork. Brian Philippy offered to explore automatic scoring using Excel formulas. This idea will be explored prior to the next AB meeting.

### **C. Use of Video in lieu of on-site observation – ad hoc committee update – Ketcherside**

History of the creation of the ad hoc committee development and the charge given to the committee was given by Dr. Ketcherside. Dr. Ketcherside provided an update that included an additional person was added (Troy Win'E due to his experience with utilizing video for training purposes). The “when” and “how” to use the video was defined by the group. It was agreed upon that a 3<sup>rd</sup> party (video professional) was not required. Video platforms were identified to best support this process (Zoom, FaceTime & Skype). A trial run was performed and discussed. The guidelines have been drafted and will be shared with the AB members. Dr. Ketcherside has identified the following banks

to partake in a beta phase: SightLife, Georgia Eye Bank, Advancing Sight (formerly known as Alabama Eye Bank), Saving Sight, and the Eye Bank for Sight Restoration. Once these banks have completed the beta phase, feed back to the subcommittee will be sought. These results and a more defined guideline will be submitted at the next AB meeting.

**D. AOPO, AATB, EBAA collaboration to reduce auditing burden of shared inspection criteria – DeMatteo**

The subcommittee that was formed (Jennifer DeMatteo, Linda Martin, Donna Drury, Marcy Dimond) had met and joined 1 conference call with the other representatives from each organization (AOPOA, AATB, EBAA). The group discussed the “common” areas of an inspection. There was a follow up to be completed by the other organizations and now awaiting to receive the inquiries to determine next steps.

**IV. New Business**

**A. Non-Member Accreditation Discussion – Corcoran**

Kevin Corcoran reported that EBAA anticipates the need to accredit non-member eye banks in the foreseeable future. He explained that EBAA’s accreditation is widely considered an essential requirement for banks to successfully place tissue, so we cannot deny accreditation to non-members without being exposed to risk of an antitrust claim. Because the accreditation process is underwritten by members’ dues, EBAA can charge non-members more to be accredited. There were three areas of expenses that the EBAA considered, Application Fee, Inspection Fee, and Expense for Travel of the AB team. Kevin went on to say that the EBAA is considering accrediting non-member banks in the future. Discussion was then opened up to the audience. Dr. Mian inquired about the value to EBAA to accredit non-members; Kevin stated that this would enable the association to still evaluate the non-member’s processes to ensure the quality of tissue is at a high level. Chris Stoeger inquired if there was an increase of non-member eye banks requesting to be accredited, does he feel that EBAA can handle that case? Kevin responded that was not an issue at this time because there have not been a large number of inquiries. Dr. Van Meter added that the way the inspections are structured and scheduled an addition to the current numbers could be accommodated. Dr. Mian then asked if this was going to be opened up to US-based or global based eye banks as well? Kevin stated that there are only US-based inquiries at this time, a few international eye banks have shown interest. A question was asked about international eye banks and if EBAA has the capability to advise given the different practices in Europe and elsewhere. One example is organ culture storage media. Dr. Rhee mentioned that the Venice Eye Bank has been EBAA accredited at some point in the past, so there is demonstrated capability. Dr. Chris Sales asked how EBAA will ensure that non-members maintain their accreditation after first receiving it. Chris Stoeger inquired about the timeline to when this may start, Kevin responded that AB’s leadership is developing a proposal and that he hopes to have more information at the next EBAA meeting in the fall. Beth Binion suggested that the AB have some type of assurance the non-member bank can submit documentation showing that they are following a medical standard. Brian Phillipy inquired about nonmembers having the opportunity to serve on EBAA boards or committees. Kevin responded that committee members are appointed by EBAA’s Chair and approved by the Board of Directors, so there would be oversight through the process. Dr. Van Meter inquired about having the nonmembers having access to EBAA forms & documents and if so,

would there be a fee associated? Kevin stated that current practice is that EBAA shares Medical Standards globally with no charges. Kevin then put the discussion back into context and explained that CorneaGen's may be ineligible for membership in the future and this was the catalyst for the initial discussion. Dr. Mian suggested that non-members would have a maximum of 1-year of accreditation.

## **V. Late Additions**

Brian Philippy submitted one late addition regarding Donor Log Reviews. This was a tool that Brian had developed to be used for a guide to the AB members and would be made available to all inspectors on the EBAA website.

## **VI. Adjournment of Business Meeting**

Hearing no other questions or comments, Chris Ketcherside closed the business meeting and reminded those in attendance that the next section would be limited to AB members only.

## **VII. Closed Session / Spring 2019 Inspection Cycle – Reports of Findings**

### **A. 18 Banks were inspected this round.**

Inspectors presented observations of the banks with findings. All 18 banks received a 3-year accreditation status.

- 4 Banks with "No Findings" or 100%
- 14 Banks with "Findings"
- There were no potential threats cited during this cycle

Minutes submitted by AB Co-Vice Chair, Kyle Mavin, CEBT

## **Forms Committee**

### **Report to Accreditation Board October 2019 Meeting**

Chris Stoeger, AB Co-Chair, tasked the Forms Committee with reviewing the Staff Worksheet from the Pre-Inspection Questionnaire and deciding whether improvements were needed. Members of the Forms Committee include Beth Binnion (chair), Vicki Adler, Alan Blake, Curt Coughlin, and Jennifer DeMatteo. Thanks to all members for the review, comments and suggestions!

#### History

Chris was looking at the Staff Worksheet, and in light of the changes made to the Medical Standards, more clearly separating tissue suitability from donor eligibility, asked if this form could be updated and made to follow a similar logic. The Forms Committee exchanged several emails regarding the rationale of the Worksheet and how it might be improved. A draft of the new, and hopefully improved, version of the Worksheet follows this report, along with the minor associated change to the PIQ instructions and PIQ/SIQ answer sheet.

#### Summary of Worksheet Changes

- Added Dates of Employment - will better assure we have received all appropriate years of OSHA training, annual competencies, etc.
- Removed Certificate/Degree - felt this was more appropriately reviewed at the bank when looking at training records to assure appropriate training and background
- Added Y/N for whether staff member is a CEBT
- Changed Donor Screening to Initial Donor Screening to more clearly separate this from eligibility determination. (The Committee felt the term “Donor Screening” by itself was too vague.)
- Since whole eye slit lamping is fairly rare, but still takes place, we simplified by making the Slit Lamp category be “Eye/Cornea” instead of separating them.
- In keeping with the new separation in Medical Standards, and in keeping with the practice in many banks, we created a separate column for performance of Tissue Suitability Determination and Donor Eligibility Determination.
- The Worksheet has been re-ordered to flow from initial screening to final determinations to better reflect the usual course of a donor review.

#### PIQ/SIQ and PIQ Instruction Changes

- A suggestion was made to have banks send an organizational chart as part of the Staff section and the Forms Committee thought this was an excellent suggestion. This has been added to the PIQ Instructions and the PIQ/SIQ response sheet.

**PRE-INSPECTION QUESTIONNAIRE WORKSHEET**

**QUESTION #2-A: STAFF** Please list the names of all staff authorized by the eye bank to perform identified functions and indicate employment status (e.g., full time, part time, on call).

NAME	EMPLOYMENT STATUS	DATES OF EMPLOYMENT	CEBT Y/N	INITIAL DONOR SCREENING	RECOVERY/PROCESSING						TISSUE EVALUATION		DETERMINE FINAL TISSUE SUITABILITY	DETERMINE FINAL DONOR ELIGIBILITY
					IN SITU EXCISION	ENUCLE- ATION	C-S DISC IN LAB	EK PROC	DMEK PROC	OTHER PROC	SLIT LAMP EYE/CORNEA	SPECULAR		



2. Please provide the following:

- C1.100-C1.300      **2-A. STAFF:** Please provide the requested information for individuals performing the identified functions in the attached chart labeled WORKSHEET 2-A. Also, please provide your current organizational chart.
- C1.300      **2-B.** For all authorized staff performing eye bank functions, provide written statement from the Medical Director or designee specifying which procedures each individual is qualified to perform independently, including suitability and release of tissue for transplant.
- C2.000      **2-C.** Provide documentation that the person (or persons) conducting annual competency reviews is a CEBT or is an individual who has been qualified by a CEBT who is part of the organization's quality program.
- C1.200      **2-D.** Provide documentation that the Staff Trainer has been observed annually by the Medical Director.

3. Please provide the following information:

- C1.200      **3-A.** Name of Medical Director
- C1.200      **3-B.** Provide documentation of Medical Director qualifications (corneal fellowship, demonstration of expertise in corneal surgery, OR documentation of a consulting relationship with an ophthalmologist who has completed a corneal fellowship).
- C1.200      **3-C.** Name and qualifications of back-up Medical Director.
- C1.300      **3-D.** If the Medical Director fulfills the role of CEBT in a supervisory position, provide documentation of current certification.
- C3.500      **3-E.** If the facility performs specialized or specific eye banking functions, provide documentation that it has a Medical Director or has access to a Medical Director through a documented consultative relationship with an accredited organization.

4. Please submit the following documentation:

- C1.200      **4-A.** A copy of the Medical Director's certificate of attendance at the Medical Directors' Symposium of an EBAA Annual Meeting at least once every three (3) years and a Medical Advisory Board meeting once every three years in the time period preceding this scheduled site inspection.
- C1.300      **4-B.** Copy/copies of the certification/recertification of the eye bank's CEBT in a supervisory role covering the three (3) years preceding this scheduled site inspection.

# SITE INSPECTION QUESTIONNAIRE

## Section 1. Pre-Inspection Materials

**After reviewing the answers submitted by the bank, indicate whether the information complies with EBAA Medical Standards in the space provided**

			Yes	No	N/A	Tier	PT/SO
D1.200	1-A	Applicable information for all INFECTIOUS DISEASE TESTING providers utilized since last inspection? ( <b>Worksheet 1-A</b> )					
C3.300, C3.510, C3.700	1-B	Acceptable information for providers of ALL OTHER SERVICES (i.e. sterilization; biohazardous waste disposal according to state and federal regulations; eye banking functions provided by another eye bank or entity) utilized since last inspection? ( <b>Worksheet 1-B</b> )					
C1.300, C2.000	1-C	Acceptable information for NON-EMPLOYEES providing recovery, preservation and/or processing services utilized since last inspection? ( <b>Worksheet 1-C</b> )					
C1.100- C1.300	2-A	Completed information provided for authorized staff and organizational chart provided? ( <b>Worksheet 2-A</b> )					
C1.300	2-B	Written statement from the Medical Director or Medical Director designee specifying which procedures each individual staff member is qualified to perform independently, including determination of suitability and release of tissue for transplant?					SO
C2.000	2-C	Is the person conducting the annual competency reviews for all remaining skills a CEBT or an individual who has been qualified by a CEBT who is part of the organization's comprehensive quality program?					SO
C1.200	2-D	Observation of Staff Trainer annually by the Medical Director?					SO
C1.200	3-A	Name of Medical Director?					
C1.200	3-B	Qualifications of Medical Director?					
C1.200	3-C	Name and qualifications of back-up Medical Director?					
C1.300	3-D	Documentation of Medical Director CEBT?					
C3.500	3-E	If the facility performs specialized or specific eye banking functions, does it have a Medical Director or access to a Medical Director through a documented consultative relationship with an accredited organization?					PT
C1.200	4-A	Valid EBAA provided documentation of Medical Director attendance, within the past three years, at a Medical Director Symposium and a Medical Advisory Board Meeting?					SO
C1.300	4-B	Valid CEBT certificate covering each year since last inspection?					
B1.000	4-C	Valid copy of FDA registration for each year since last inspection?					
C3.200	4-D	Valid annual certificate for Processing Environment(s) per MS E1.200 for each year since last inspection?					
C3.200	4-E	Valid documentation that the continuous temperature recorder has been calibrated at least annually against a NIST thermometer for each year since last inspection?					
F1.200	4-F	Valid documentation of annual calibration of endothelial cell counting equipment for each year since last inspection?					
J1.000	4-G	Sample labels submitted for all tissue distributed?					
B1.000	4-H	Documentation that ICCBBA registration for FIN has been maintained for each year since last inspection.					
J1.000	5	Does the numbering system provide for a unique ISBT 128 Tissue Identifier for each surgical tissue or fraction thereof?					SO
D1.200	6	Was the plasma dilution worksheet / algorithm problem solved correctly?					SO
M1.300- M1.500	7-A	Attached sample forms used to record donor and recipient information?					
L1.100	7-B	Does the Tissue Report Form include all of the following? (Check missing items)					SO
		<i>Unique ISBT 128 Tissue Identifier</i>					
		<i>Name of source eye bank</i>					
		<i>Location of eye bank</i>					
		<i>Telephone number</i>					
		<i>Type of storage solution</i>					
		<i>All dates and times written as YYYY-MM-DD HH:MM</i>					
		<i>Pre-cut method performed or the indicated use (e.g. EK, PLK, ALK, etc.) (if applicable)</i>					
		<i>Tissue evaluation reporting requirements according to Matrix II</i>					
		<i>Age of donor</i>					
		<i>Cause of Death</i>					
		<i>Death date and time</i>					
		<i>Preservation date and time</i>					
		<i>Additional tissue processing date and time</i>					
		<i>Date and time of cooling of ocular tissues</i>					
		<i>Slit lamp report</i>					
		<i>Specular microscopy report</i>					
		<i>Identification of enucleator, evaluator, and technicians</i>					
		<i>Name and EBAA accreditation status (including accredited functions) of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, tissue storage, evaluation, donor eligibility determination, and final distribution</i>					
		<i>Summary of records reviewed in determining suitability</i>					

PT = Potential Threat  
SO = Significant Observation